United States Department of Agriculture
Food Safety And Inspection Service
Technical Service Center
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AUDIT REPORT FOR ITALY
NOVEMBER 14 THROUGH DECEMBER 19, 2001

INTRODUCTION

Background

This report reflects information that was obtained during an audit of Italy's meat inspection system from November 14 through December 19, 2001. Forty of the 64 establishments certified to export meat to the United States and that were exporting to the United States were audited. Six of these were slaughter establishments; the other 34 were conducting processing operations. The remaining establishments that are certified to export to the United States were not actively exporting at this time and they were not included in this audit.

The last audit of the Italian meat inspection system was conducted in May 2001. The auditors found significant problems in 10 establishments, which were then designated as marginal/re-review at the next audit. The auditors found sanitation and other conditions to be so serious in eight establishments that these establishments were delisted by the Government of Italy (GOI). In addition, the auditors found that implementation of Hazard Analysis and Critical Control Point (HACCP) systems was deficient in 22 of 27 establishments audited.

The major concerns from the May 2001 audit were the following:

1. The lack of daily inspection coverage in establishments producing products for export to the U.S.
2. Inadequate inspection system controls, including the denaturing of condemned or inedible products, enforcement of humane slaughter laws, use of inspection procedures to check for disease, and carcass and offal inspection requirements.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. The lack of monthly supervisory reviews of most certified establishments.
5. The continuing problems with the implementation and maintenance of Sanitation Standard Operating Procedures (SSOP) in certified establishments.
6. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
7. Deficiencies in the *Salmonella* sampling and testing program.
8. Deficiencies in Italy's microbiological laboratory testing programs.

Italy exports only processed pork products to the United States. Fresh pork may not be exported due to the presence of hog cholera and swine fever in Italy. From January 1 to

September 30, 2001, Italian establishments exported 3,593,523 pounds of pork products to the United States. Port-of-entry rejections were for unsound condition (0.02%), miscellaneous defects (0.05%), and missing shipping marks (0.05%).

PROTOCOL

This on-site audit was conducted in four parts. One part involved visits with Italian national meat inspection officials to discuss oversight programs and practices, including enforcement activities. The second part involved on-site visits to 40 establishments: 34 processing establishments (5L, 23L, 25L, 41L, 90L, 151L, 160L, 172L, 205L, 316L, 335L, 363L, 368L, 442L, 476L, 480L, 492L, 500L, 513L, 514L, 550L, 586L, 632L, 649L, 683L, 688L, 714L, 720L, 744L, 758L, 989L, 1170L, 1217L, and 1223L) and six slaughter establishments (92M/S, 272M/S, 304M/S, 312M/S, 643M/S, and 791M/S). All six of Italy's certified slaughterhouses and another seven processing establishments were selected for audit because of serious concerns arising from the previous on-site audits. Twenty-seven additional establishments were selected randomly from certified establishments actively exporting to the United States. The third part involved visits to nine government laboratories, all of which culture field samples for the presence of generic *Escherichia coli* (*E. coli*) and *Salmonella*. Two of the nine laboratories also perform analytical testing of field samples for the national residue-testing program. The fourth part involved visits to six regional inspection offices and four local inspection offices.

Program effectiveness determinations focused on five areas of risk: (1) sanitation controls, including the implementation and operation of Sanitation Standard Operating Procedures (SSOP), (2) animal disease controls, (3) residue controls, (4) slaughter/ processing controls, including the implementation and operation of HACCP systems and the generic *E. coli* testing program, and (5) enforcement controls, including the testing program for *Salmonella*. Italy's inspection system was assessed by evaluating these five risk areas.

During all on-site establishment visits, the auditors evaluated the nature, extent, and degree to which findings impacted on food safety and public health, as well as overall program delivery. The auditors also determined if establishment and inspection system controls were in place.

To gain an accurate overview of the effectiveness of inspection controls, FSIS requested that the audits of the individual establishments be led by the inspection officials who normally conduct the monthly reviews for compliance with U.S. specifications. A Ministry of Health (MOH) official requested that FSIS lead this current audit and FSIS agreed. In the future, MOH officials will lead the audits of the individual establishments.

RESULTS AND DISCUSSION

Summary

Forty establishments were audited. The auditors found sanitation and other conditions to be so serious in four establishments that the establishments were delisted by the GOI (160L, 363L, 500L, and 989L). The auditors found serious problems in five establishments. These establishments were designated as marginal/re-review during the next audit (172L, 492L, 649L, 744L, and 758L).

Six Regional Inspection Offices and four local inspection offices were visited. The seventh Regional Office declined the visit citing other commitments. The following six Regional Offices were visited: Lombardia, Lazio, Emilia-Romagna, Friuli-Venezia Guilia, Toscana, and Marche. Four local inspection offices were visited, one each within the following regions: Lombardia, Lazio, Emilia-Romagna, and Toscana.

As stated above, numerous major concerns had been identified during the May 2001 audit of the Italian meat inspection system. During this current audit, the auditors determined that no significant improvements were made by the GOI since the May 2001 audit. Some improvements were noted in individual establishments' implementation and operation of HACCP and SSOP. These improvements may be attributed to a working group formed by the MOH after the May 2001 audit to address the May 2001 audit findings or to training provided through Italian trade associations directly to establishment personnel. Despite the improvements noted, the Italian meat inspection system still has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in this report.

Details of audit findings, including compliance with HACCP, SSOPs, and testing programs for *Salmonella* species and generic *E. coli*, are discussed later in this report. Data collection instruments for SSOP, HACCP, and testing programs for generic *E. coli* and *Salmonella* can be found in Attachments A, B, C and D respectively. Individual establishment reports can be found in Attachment F.

Entrance Meetings

On November 14, 2001, an entrance meeting was held at the Ministry of Health in Rome. The Italian government participants were Dr. Silvio Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Dirigente II Livello- Direttore Ufficio VIII; Dr. Pietro Noe, Veterinario Dirigente I Livello-Ufficio VIII, DANSPV; Dr. Piergiuseppe Facelli, Veterinario Dirigente II Livello, Direttore Ufficio III, DANSPV; Dr. Angelo Di Donato, Veterinario Dirigente I Livello, Ufficio III, DANSPV; Dr. Alessandra Di Sandro, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Pinto Ornella, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Alessandro Cascone, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Lidia Cecio, Veterinario Dirigente I Livello, Ufficio VIII, DANSPV; Dr. Raffaella Augelli, Veterinario Coadiutore Ufficio VIII, and Ms. Marina Paluzzi, Interpreter.

The United States government participants were Dr. Faizur R. Choudry, International Audit Staff Officer, Technical Service Center (TSC), Food Safety and Inspection Service (FSIS); Dr. Oto Urban, International Audit Staff Officer, TSC, FSIS; Ms. Ann Murphy, Agricultural Attaché, United States Embassy, Rome; and Mr. Sandro Perini, Agricultural Specialist, United States Embassy, Rome.

Topics of discussion at the first entrance meeting included the following:

- Welcome by Dr. Silvio Borrello, Dirigente II Livello, and explanation of the Italian meat inspection system.
- Discussion of the previous audit report.
- The audit itinerary and travel arrangements.
- Training programs for veterinary meat inspection officials for pathogen reduction and other food safety initiatives such as SSOP, HACCP programs, generic *E. coli* testing and *Salmonella* testing.
- The auditors provided (a) a copy of the current Quarterly Regulatory and Enforcement Report, (b) FSIS Directive 6420.1, Livestock Post-mortem Inspection Activities-Enforcing the Zero Tolerances for Fecal Material, Ingesta, and Milk, and (c) FSIS Notice 22-01, Procedures for FSIS Personnel during Pre-implementation Period for "Retained Water in Raw Meat and Poultry Products; Poultry Chilling Requirements."

On November 26, 2001, a second entrance meeting was held at the Ministry of Health in Rome. The Italian government participants were Dr. Silvio Borrello, Dipartimento Alimenti Nutrizione E Sanita' Pubblica Veterinaria (DANSPV), Dirigente II Livello- Direttore Ufficio VIII and Dr. Piergiuseppe Facelli, Veterinario Dirigente II Livello, Direttore Ufficio III, DANSPV. The United States government participants were Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS, and Mr. Franco Regini, Agricultural Specialist, Foreign Agricultural Service, United States Embassy, Rome.

Topics of discussion at the second entrance meeting included the following:

- Welcome by Dr. Silvio Borrello, Dirigente II Livello, and explanation of the Italian meat inspection system.
- Discussion of the previous audit report.
- The audit itinerary and travel arrangements.

<u>Government Oversight and Responsibility</u>

FSIS regulations require that foreign countries that request eligibility to export meat to the United States or to maintain their current eligibility be organized and administered by the national government. More specifically, the National government must have an inspection system consisting of an organizational structure with staffing to ensure uniform enforcement of the requisite laws and regulations in all establishments producing product for export to the United States. Second, the national government must have ultimate control and supervision over the official inspection activities of all employees and licensees. Third, the national

government must ensure the assignment of competent, qualified inspectors. Fourth, national inspection officials must have the authority and responsibility to enforce the laws and regulations governing meat inspection, and fifth, the country must have adequate administrative and technical support to operate its inspection program.

Our auditors noted the following.

1. Organizational Structure and Staffing

The Italian meat inspection system is organized in three levels. The first level consists of the Ministry of Health, which includes Veterinary Services. It is this level of government that FSIS holds responsible for ensuring that FSIS requirements are implemented and enforced. The second level consists of Regional Offices. There are 21 Regional Offices (19 regions and two provinces). Each Regional Office is autonomous and independent from the MOH. Among Regional Offices, there are differences in organization, staffing and available resources. Within each Regional Office, a third level exists known as the Aziende Sanitarrie Locali (ASL), which are also autonomous. The ASLs provide the inspectors for actual inspection activities.

There are generally two levels of employment of inspectors and veterinarians at the ASLs and the Regional Offices. These two levels consist of a Director of the ASL or Region and staff veterinarians. Each level appears to be independent of the other. If a veterinarian assigned to the establishment fails to properly discharge his/her responsibilities, the Director seems to have little or no authority to take proper disciplinary action. The auditor was told that if such a situation arises, the MOH will decertify the establishment and the establishment may then sue the veterinarian to recover the damages.

All inspection veterinarians and inspectors in establishments certified by Italy as eligible to export meat products to the United States were MOH regional and local government employees, receiving no direct remuneration from either industry or establishment personnel.

The MOH has responsibilities for participating and negotiating new or revised inspection legislation, interpreting and clarifying inspection-related European Commission Directives, United States requirements and Italian laws and regulations, and transmitting these documents to the Regional Offices. Although compliance is requested by the MOH, each Regional Office and ASL may create their own corresponding circulars, forms, and instructions, provided they meet the minimum requirements outlined by the MOH.

Although an organizational structure is in place for headquarters, the Regional Offices, and the ASLs, staffing at the MOH and the Regional Offices appears inadequate. As stated above, Regional Offices vary in staffing and available resources. It appears that this inhibits the ability of the inspection officials to enforce European Commission Directives and U.S. inspection requirements.

2. Ultimate Control and Supervision

On November 6, 2001, the MOH sent a circular to all Regional Offices requesting that they develop inspection procedures as described in the circular and to adopt procedures and forms for inspection that meet the provisions in the circular. However, since the circular was only issued one week before our auditors arrived in Italy, the Regional Offices had not had time to implement the circular. In one Regional Office, the circular could not be located.

The supervision and authority delegated by each Regional Office and ASL varies. Our auditor found that government inspectors and veterinarians that work at the establishments are generally not accountable to the ASL, the Regional Office, or the MOH. The inspectors that actually perform the routine inspection activities are hired and paid by the ASL. The ASL or the Regional Office generally cannot discipline or fire poor performing employees but can only recommend action to the Director General of the ASL against such an employee.

Although detailed instructions are issued by the MOH for the Regions and the ASLs on requirements to be carried out by Regions or ASLs, including on-site visits to establishments, the MOH and the ASLs seems to rely heavily upon the results of FSIS audits of individual establishments rather than meeting the MOH's requirements. Italy's inspection system appears to be reactive for maintaining compliance rather than preventive. For example, the MOH verified compliance with U.S. requirements only in the slaughter establishments found unacceptable during the May 2001 audit. The MOH did not conduct any other verification activities with regard to determining compliance of processing establishments that were found to be unacceptable or marginal/re-review.

There appears to be no regular or uniform verification procedure by the MOH of the circulars sent to the Regional Offices and ASLs to assure that the circulars have been implemented. For example, two microbiology directors indicated their willingness and ability to perform analyses according to U.S. methodology. However, both also said that they had not been instructed by the MOH to implement U.S. methodology and would not change their procedures until requested to do so by the MOH.

3. Assignment of Competent, Qualified Inspectors

In 29 processing establishments, the GOI was not providing daily inspection coverage. Inspectors were visiting establishments at variable frequencies such as two to three times a week, once a week, twice a month, or once a month. In four of the regions audited, the auditor was told that there were not enough inspection resources to provide daily inspection coverage.

Once inspectors are assigned, the GOI does not have a uniform method to prioritize and assign inspection tasks. The performance of inspection tasks at an establishment is solely dependent upon the judgment of the inspector.

In all 40 of the establishments audited, the GOI inspectors were not aware of deficiencies until pointed out to them by the auditors. In addition, in nine of the 40 establishments GOI inspectors did not take corrective actions when deficiencies were discovered.

The auditor noted that all government veterinarians must have completed at least three years of specialized training in food inspection prior to hiring. Additionally, some Regional Offices have provided opportunities for formal training in HACCP and other food science disciplines. However, considerable training in basic sanitation principles and FSIS' Pathogen Reduction requirements is still needed. This need for additional training is evidenced by the fact that the majority of establishments continue to have serious problems with basic sanitation, which has resulted in direct product contamination and the potential for direct product contamination. In addition, the auditor found that most inspectors and veterinarians assigned to certified establishments do not understand how to implement or have not been required to implement FSIS' Pathogen Reduction requirements, which include SSOP, HACCP, generic *E. coli* testing, and *Salmonella* testing.

The auditor was advised that there is no supervision of inspectors and veterinarians in the Regional Offices and the ASLs. The auditor was told that all government veterinarians are expected to operate at a high level of professionalism and trust. The performance of these veterinarians is rarely questioned. Actual visits to determine competence by the Regional Office are not routinely performed or documented and are not part of any written supervisory plan.

4. Authority and Responsibility to Enforce the Laws

Prior to our May 2001 audit, ASLs had the responsibility for approving establishments for export to the U.S. and to withdraw such approval for cause. Subsequent to our May 2001 audit, the MOH assumed this responsibility. Under the direction of the MOH, any new establishment that wishes to export to the U.S. has 90 days to comply with U.S. requirements. The ASL monitors the establishment and then notifies the MOH, either through the Regional Office or directly, of the decision to certify or not certify the establishment for U.S. export. The MOH generally does not visit these establishments on-site but will certify the establishment based on the ASL's recommendation.

For example, an establishment in the Lazio Region, which had been delisted by the GOI at FSIS' recommendation during the May 2001 audit, was recertified prior to our November 2001 audit without verification of its acceptability by the MOH. This establishment had not undertaken any corrective actions since the last audit and was again found unacceptable by FSIS during this new audit. An establishment in the Marhe Region was certified by the MOH but was delisted just prior to the start of the current audit. When asked about the situation, the auditor was told that the establishment was decertified because the Regional Office had found some problems in the establishment that were not known to MOH at the time of certification. The MOH has advised that in the future it will verify the acceptability of all new establishments by conducting on-site visits to the establishments before they are certified for export.

The only change in the organizational structure or upper levels of the MOH was the hiring of five new staff officers (3 full time and 2 part time) subsequent to the May 2001 audit. This brings the total headquarters staff to six employees. The auditor was told that once training had been completed for these new employees, the MOH would be able to conduct monthly supervisory reviews of the U.S. certified establishments to verify the implementation of FSIS requirements.

5. Adequate Administrative and Technical Support

The auditors were concerned over the inability of the MOH to provide basic resources for the FSIS audit, which resulted in industry personnel transporting the auditors to the establishments. The allocation of appropriate resources to support a third party audit still remains.

Establishment Audits

Establishment Operations by Establishment Number

The following operations were being conducted in the 40 establishments visited on-site:

Pork slaughter and boning - six establishments (92M/S, 272M/S, 304M/S, 312M/S, 643M/S, and 791M/S)

Pork de-boning and prosciutto/cooked hams – 34 establishments (5L, 23L, 25L, 41L, 90L, 151L, 160L, 172L, 205L, 316L, 335L, 363L, 368L, 442L, 476L, 480L, 492L, 500L, 513L, 514L, 550L, 586L, 632L, 649L, 683L, 688L, 714L, 720L, 744L, 758L, 989L, 1170L, 1217L, and 1223L)

Forty establishments were visited. Four establishments (160L, 363L, 500L, and 989L) were found to be unacceptable because of critical sanitation problems, findings of direct product contamination, and noncompliance with basic HACCP requirements and were delisted by the GOI. Five establishments (172L, 492L, 649L, 744L, and 758L) were rated marginal/re-review because of deficiencies regarding sanitation, condition of facilities, and noncompliance with HACCP requirements.

Laboratory Audits

During the laboratory audits, emphasis was placed on the application of procedures and standards that were equivalent to U.S. requirements. Information about the following risk areas was also collected:

1. Government oversight of accredited, approved laboratories.
2. Intra-laboratory quality assurance procedures, including sample handling.
3. Methodology.

The Instituti Zooproficlattici Sperimentali Laboratories in Torino and Brescia were audited on December 12 and 13, 2001, respectively. Both of these laboratories perform analytical testing of field samples for the national residue control program. Effective controls were in place for sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, and proficiency testing. The methods used for the analyses were acceptable. No compositing of samples was done. More detailed information on audit findings can be found under "Residue Controls" further in this document.

Italy's microbiological testing for *Salmonella* was being performed in government Instituti Zooproficlattici Sperimentali (IZS) laboratories. Nine of these laboratories were visited. The nine included the residue laboratories in Torino and Brescia as they also perform microbiological testing. Eight of these nine laboratories perform analyses for the GOI on product intended for export to the United States.

Italy has advised FSIS that it adopted all FSIS requirements except the following equivalent measures: The government laboratories use ISO 6579 and AOAC 967.25 methods to analyze samples for *Salmonella.* During the May 2001 audit, FSIS found that laboratories were using modified analytical methods that had not been sent to FSIS for an equivalence determination.

More detailed information on audit findings can be found under "Slaughter/Processing Controls" and "Enforcement Controls" further in this document.

SANITATION CONTROLS

As stated earlier, the auditor focuses on five areas of risk when assessing a foreign country's inspection system. The first of these risk areas that the auditor reviews is Sanitation Controls. These controls include the implementation and operation of SSOP programs in certified establishments, all aspects of facility and equipment sanitation, actual or potential instances of product cross-contamination, personal hygiene and practices, and product handling and storage.

Based on the on-site audits of establishments, Italy's inspection system had controls in place for water potability records; chlorination procedures; back-siphonage prevention; separation of operations; temperature control; work space; ventilation; ante-mortem facilities; welfare facilities; and outside premises.

In the following areas, inspection system controls were not adequate:

Sanitation Standard Operating Procedure (SSOP)

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment A).

The SSOP in the 40 establishments were found to meet the basic FSIS regulatory requirements, with the following deficiencies.

- In 31 establishments, GOI meat inspection officials were not adequately monitoring or verifying the adequacy and effectiveness of the pre-operational and operational sanitation SSOP. The inspectors were performing pre-operational and operational sanitation SSOP with variable frequencies, such as once a week, twice a month, once a month and four times a year. *This is a repeat deficiency from the May 2001 audit.*
- In 12 establishments, the records for SSOP operational sanitation and any corrective action taken were not being maintained. *This is a repeat deficiency from the May 2001 audit.*
- In three establishments, the written SSOP procedure did not address pre-operational sanitation. *This is a repeat deficiency from the May 2001 audit.*
- In three establishments, the written SSOP did not address operational sanitation. *This is a repeat deficiency from the May 2001 audit.*
- In two establishments, the SSOP procedure did not identify the individual responsible for implementing and maintaining the activities. *This is a repeat deficiency from the May 2001 audit.*

Cross-Contamination: In the area of cross-contamination, actual product contamination and the potential for product contamination was found in 26 out of 40 establishments audited.

Examples of findings of actual product contamination include:

- In nine establishments, insanitary equipment was directly contacting edible product in the processing rooms, fresh product receiving rooms, and cold boning rooms. For example, working tables and frames of tables, containers for edible product, meat grinding equipment, band saw, conveyor belt for edible product, brine injection equipment, racks, and molds for hams were found with flaking paint, rust, fat, pieces of meat, grease, and dirt from the previous days' operation. In some establishments, the conveyor belt for edible product was cracked and deteriorated in the salting rooms and product receiving room. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In five of nine establishments, this is a repeat deficiency*.

- In nine establishments, exposed edible-product was contacting an unclean fork lift, inedible product containers, posts, dirty legs of racks for edible product that stacked on top of each other, unclean protective covering for air circulation system, walls and doors during handling and transportation in the de-boning rooms, ham salting rooms, ham curing rooms, and fresh ham receiving rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In four of nine establishments, this is a repeat deficiency.*

- In three establishments, dripping condensate from overhead refrigeration units, ceilings, rails, pipes, and beams that were not cleaned/sanitized daily, was falling onto exposed edible product in the cooler, fresh product receiving room, corridors, defrosting room,

cooking room, and smoking rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In two of three establishments, this is a repeat deficiency.*

- In three establishments, sanitizers were not maintained at the required temperature (82ºC) in the boning rooms. In one other establishment, the sanitizer was not in operation during processing operations. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In two of three establishments, this is a repeat deficiency.*

- In one establishment, water was falling onto hog carcasses from the carcass splitting saw at the carcass splitting station. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *This is a repeat deficiency for this establishment.*

Examples of findings of <u>potential</u> cross-contamination of product include:

- In six establishments, overhead ceilings in the processing rooms and ham salting rooms were observed with an accumulation of pieces of fat, meat, flaking paint, and dirt. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of six establishments, this is a repeat deficiency*.

<u>Personal Hygiene and Practices</u>: In the area of personal hygiene and practices, the following deficiencies were noted.

- In eight establishments, several employees were observed picking up pieces of meat from the floor, handling unclean inedible product containers, a fork lift, and trash containers and, without washing their hands, handling edible product.
establishments, plastic packaging materials, cartons, and strings for hanging hams were contacting the floor and inedible product containers in the packaging rooms.
establishment, a few employees were not using hygienic work habits. For example, paper towels were kept
another establishment, edible product was not unpacked in a sanitary manner to prevent

June 1964.

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exposed product contamination. In another establishment, street clothes and working clothes were not kept separate in the locker. This is a n
Directive 64/433/EEC of 26 June 1964.

<u>Product Handling and Storage</u>
deficiencies were noted.

- In 11 establishments, edible product that contacted the floor (dropped meat) was not reconditioned in a sanitary manner before being added to the edible product. The f
for reconditioning dropped meat was inadequate. There was no designated area with light, no written proper procedure, and no hand washing or sanitizing facilities. This is a

noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of 11 establishments, this is a repeat deficiency.*

- In 11 establishments, edible and inedible product containers were not identified to prevent possible cross-contamination or cross utilization in the boning room, ham slicing room, and ham salting rooms, and processing rooms. *In two of 11 establishments, this is a repeat deficiency.*

- In eight establishments, pest control prevention was inadequate. For example, in one establishment, the dry storage room for packaging materials had no front and side walls (plastic curtains) to prevent the entry of rodents and other vermin. Mice droppings, urine, cobwebs, dirt and debris were observed and packaging materials were not stored on racks high enough and away from walls to monitor pest control and sanitation programs. Evidence of rodent infestation was observed on several dates in the personnel office and welfare rooms by a private pest control company during their routine monitoring program. Rodenticides were replaced in the bait boxes but no other effort was made to take corrective or preventive measures either by the pest control company, establishment personnel, or by the GOI meat inspection officials. In another establishment, the door in the product receiving room was not effectively shut. The vent in the smoking room was broken and flies were observed in the processing and packaging rooms. In five establishments, gaps at the bottoms and sides of doors in the boning rooms, casing rooms, product receiving rooms, emergency doors leading to the processing rooms, and dry storage rooms were not sealed properly to prevent the entry of rodents and other vermin. In one other establishment, cobwebs were observed in the ham curing room. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *In one of eight establishments, this is a repeat deficiency.*

Establishment Facilities: In the area of maintenance of establishment facilities, the following deficiencies were noted.

- In four establishments, light was inadequate and not shadow proof at the hog head, viscera and carcass inspection stations in the slaughter room. *In two out of four establishments, this is a repeat deficiency.*

- In one establishment, walls and covings were broken in numerous places in the coolers and processing rooms. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964.

ANIMAL DISEASE CONTROLS

The second of the five risk areas that the auditor reviews is Animal Disease Controls. These controls include ensuring adequate animal identification, control over condemned and restricted product, and procedures for sanitary handling of returned and reconditioned product. Except as noted below, Italy's inspection system had adequate controls in place.

There were reported to have been no outbreaks of animal diseases with public health

approximately 100,000 bovine were tested for Bovine Sponigiform Encephalopathy and 30 were found positive. Italy is prohibited from exporting beef to the U.S. In addition, Italy is not free from Hog Cholera or Swine Vesicular Disease. Although Italy is currently free of

border with a country that is not free of Foot and Mouth Disease.

The following deficiencies were noted.

In two out of six slaughter establishments, the mandibular lymph nodes of hog heads

lymph nodes and spleen were not palpated during post mortem inspection. This is a noncompliance with Council Directive 64/433/EEC of 26 June 1964. *This is a repeat deficiency from the May 2001 audit.*

- In all 40 establishments, inedible product was not denatured or de-characterized or placed under security before shipping for rendering. In one establishment, inedible product was kept in open containers outside the premises. *This is a repeat deficiency from the May 2001 audit.*

RESIDUE CONTROLS

The third of the five risk areas that the auditor reviews is Residue Controls. These controls include sample handling and frequency, timely analysis, data reporting, tissue matrices for analysis, equipment operation and printouts, minimum detection levels, recovery frequency, percent recoveries, and corrective actions.

The Instituti Zooproficlattici Sperimentali (IZS) Laboratories in Torino and Brescia were audited on December 12 and 13, 2001, respectively.

The following deficiencies were noted.

- The standards book for chlorinated hydrocarbons, polychlorinated biphenyls, trace elements, hormones, sulfonamides, chloramphenicol, and ivermectin was not properly maintained for the quality assurance program. For example, when the analyst prepares the solutions, the standards book was not signed and verified by the supervisor before the solutions were used. Corrections to the standards book were not made by means of a single line through the incorrect entry with the correct information written above or after the error.

- When percent recovery results fell below the established acceptable range limit for chlorinated hydrocarbons, polychlorinated biphenyls (PCBs), hormones, arsenic, and chloramphenicol, no corrective actions were taken or documented for the quality

assurance program. *This is a repeat deficiency from the May 2001 audit with regard to percent recovery for PCBs.*

- The check sample program did not meet FSIS or EU requirements. In most sections of the laboratories, regular spiked samples that are routinely run as part of a sample set were erroneously considered to be check samples. No intra-laboratory and/or inter-laboratory check samples for the quality assurance program were performed for chlorinated hydrocarbons, polychlorinated biphenyls, trace elements, hormones, sulfonamides, chloramphenicol, antibiotics, and ivermectin except for one inter-laboratory check sample (ring test) was performed for polychlorinated biphenyls and trace elements in 2001. This is a noncompliance with Council Directive 96/23/EC of 29 April 1996.

The auditors found that Italy's National Residue Testing Plan for 2001 was being followed and was on schedule. The GOI had adequate controls in place to ensure compliance with sampling and reporting procedures and storage and use of chemicals. The methods used for the analyses were acceptable.

SLAUGHTER/PROCESSING CONTROLS

The fourth of the five risk areas that the auditor reviews is Slaughter/Processing Controls. The controls include the following areas: adequate animal identification; ante-mortem inspection procedures; ante-mortem disposition; humane slaughter; post-mortem inspection procedures; post-mortem disposition; ingredients identification; control of restricted ingredients; formulations; processing schedules; equipment and records; and processing controls of cured, dried, and cooked products. The controls also include the implementation of HACCP systems in all establishments and implementation of a generic *E. coli* testing program in slaughter establishments. Deficiencies are discussed below.

- In one out of six slaughter establishments, hogs were not stunned in such a manner that they would be rendered unconscious with a minimum excitement and discomfort such as a few hogs were observed staggering and crawling on the top of other stunned hogs and their throats were slit by the employee without any further stunning. *This is a repeat deficiency from the May 2001 audit.*

HACCP Implementation: All establishments approved to export meat products to the U.S. are required to have developed and implemented a HACCP system. Each of these systems was evaluated according to the criteria employed in the U.S domestic inspection program. The data collection instrument used accompanies this report (Attachment B).

The HACCP programs were reviewed during the on-site audits of the 40 establishments. The auditors found the following deviations from FSIS' regulatory requirements.

- In 14 establishments, the HACCP plan was not validated to determine if it was functioning as intended. *In six of 14 establishments, this is a repeat deficiency.*

- In 20 establishments, the HACCP plan did not state adequately the procedures that the establishment would use to verify that the plan was being effectively implemented and the frequencies with which these procedures would be performed. The ongoing verification activities of the HACCP program were not performed adequately either by the establishment personnel or by the GOI meat inspection officials. *In 10 of 20 establishments, this is a repeat deficiency.*

- In 13 establishments, the HACCP plan did not address adequately the corrective actions to be followed in response to deviations from critical limits. *In six of 13 establishments, this is a repeat deficiency.*

- In 12 establishments, the hazard analysis was not adequately conducted. *In one of 12 establishments, this is a repeat deficiency.*

- In 12 establishments, the HACCP plan did not adequately specify critical limits for each CCP and the frequency with which these procedures would be performed. *In four of 12 establishments, this is a repeat deficiency.*

- In six establishments, the HACCP plan flow chart did not adequately describe the process steps and product flow.

- In six establishments, the HACCP plan's record keeping system was not adequately documenting the monitoring of CCPs. *In two of six establishments, this is a repeat deficiency.*

- In three establishments, there was no adequate written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur. *In one of three establishments, this is a repeat deficiency.*

- In four establishments, the HACCP plan did not address the intended use of or the consumers of the finished product(s). *In one of four establishments, this is a repeat deficiency.*

- In three establishments, the final review of all documentation associated with the production of the product prior to shipping was not done. *In one of three establishments, this is a repeat deficiency.*

Testing for Generic *E. coli*

Italy has adopted the FSIS regulatory requirements for generic *E. coli* testing. Six of the 40 establishments audited were required to meet the basic FSIS regulatory requirements for generic *E. coli* testing. These six establishments were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment C).

The following deficiencies were noted.

- In three establishments, the carcass selection was not made randomly and use of a random method of selection was not specified in the procedure. *In three of three establishments, this is a repeat deficiency.*
- In two establishments, the sequence of carcass sponging was not being followed properly. *In two of two establishments, this is a repeat deficiency.*
- In one establishment, the procedure did not designate the employee(s) responsible for collecting the samples.

ENFORCEMENT CONTROLS

The fifth of the five risk areas that the auditor reviews is Enforcement Controls. These controls include the enforcement of inspection requirements and the testing program for *Salmonella* species.

Except as noted in this report, the GOI had controls in place for ante-mortem and post-mortem inspection procedures and dispositions; restricted product and inspection samples; disposition of dead, dying, diseased or disabled animals; shipment security, including shipment between establishments; and prevention of commingling of product intended for export to the U.S. with product intended for the domestic market.

In addition, controls were in place for the importation of only eligible livestock from other countries, i.e., only from eligible third countries and certified establishments within those countries, and the importation of only eligible meat products from other counties for further processing. Adequate controls were found to be in place for security items, shipment security, and products entering the establishments from outside sources.

Testing for *Salmonella* Species

Prior to this audit Italy had advised FSIS that it had adopted all of the FSIS requirements for *Salmonella* species testing with the sole exception of the use of different analytic methods. FSIS had determined that Italy's use of the ISO 6579 and AOAC 967.25 methods were equivalent to FSIS' requirements.

Six of the establishments audited were required to meet the basic FSIS regulatory requirements for *Salmonella* testing, and were evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument used accompanies this report (Attachment D).

The following deficiencies were noted.

- In all six slaughter establishments, *Salmonella* samples were collected by the establishment personnel under the direct supervision of government employees. The only

scenario currently approved by FSIS for Italy is the use of government employees to collect samples. *In six of six establishments, this is a repeat deficiency.*

- In two establishments, the samples were not being taken randomly.

- In two establishments, the sequence of carcass sponging was not being followed properly. *In two of two establishments, this is a repeat deficiency.*

- Microbiology methods in-use tended to be based on standard methods. However, some laboratories are modifying standard methods and are not strictly adhering to standard protocols. Modifications to standard methods are not acceptable. *This is a repeat deficiency from the May 2001 audit.*

Species Verification Testing

At the time of this audit, Italy was required to test product for species verification. Species verification testing was not being conducted in eight establishments (5L, 41L, 92M/S, 160L, 205L, 335L, 363L, and 989L). Species testing is required in any establishment that is approved to ship product to the U.S. This testing is required on products that are not readily identifiable as to source (i.e., any product that does not consist of a whole, intact muscle such as cooked sausage product or chopped and formed ham product).

Listeria monocytogenes Testing

Establishments producing ready-to-eat products are required to reassess their HACCP plans to determine if *Listeria monocytogenes* should be considered as a hazard reasonably likely to occur. All 34 processing establishments that were reviewed on-site produce ready-to-eat products and had not amended their HACCP plans to include *Listeria monocytogenes* as a hazard reasonably likely to occur.

Monthly Reviews

The internal review program was applied equally to both export and non-export establishments. Internal review visits were both announced and not announced in advance, and were conducted, at times by individuals and at other times by a team of reviewers. These reviews were being performed by the regional or local officials, and were all veterinarians. The records of audited establishments were kept in the inspection offices of the individual establishments, and copies were also kept in the regional and provincial offices.

In some establishments, only two or three reviews are conducted each year instead of monthly as required by FSIS. However, as stated earlier, the MOH has pledged to acquire the staff and resources to begin conducting monthly reviews of all certified establishments.

Inspection System Controls

The following deficiencies were noted.

- In eight establishments, periodic supervisory visits were not performed monthly. Only two to four internal reviews were conducted per year by the local officials and/or by the veterinarian assigned to different establishments in the same area. *This is a repeat deficiency from the May 2001 audit.*

- In 11 establishments, edible and inedible product containers were not identified to prevent possible cross-contamination/cross-utilization in the boning room, ham-slicing rooms, ham salting rooms, and processing rooms. *In two of 11 establishments, this is a repeat deficiency from the May 2001 audit.*

- In two establishments, incorrect labels were used. For example, in one establishment a statement on the label of Leonardo Ham declares that the hams used are from Italy, when the hams were actually imported from Denmark. In another establishment, the label approval indicates the European Union number instead of one approved for the U.S.

Exit Meeting

The exit meeting was conducted at the Ministry of Health in Rome, on December 19, 2001. The participants from Italy were Dr. Silvio Borrello, Dirigente II Livello- Direttore Ufficio VIII, Department of Food Nutrizion and Public Veterinary Health (DANSPV); Dr. Pietro Noe, Veterinario Dirigente I Livello-Ufficio VIII; Dr. Angelo Di Donato, Veterinario Dirigente I Livello, Ufficio III; Dr. Alessandra Di Sandro, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Alessandro Cascone, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Lidia Cecio, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Raffaella Augelli, Veterinario Coadiutore Ufficio VIII; Dr. Ornella Pinto, Veterinario Dirigente I Livello, Ufficio VIII; Dr. Pierantoni Marco, Assessorato Alla Sanita, Regione Emilia Romagna; Dr. Duratti Giuseppe, Assessorato Alla Sanita, Regione Friuli Venezia Giulia; Dr. Sigismondi Mariano, Assessorato Alla Sanita, Regione Lazio; Dr. Giorgioni Adriano, Assessorato Alla Sanita, Regione Lazio; Dr. Clare Norman, Assessorato Alla Sanita, Regione Lazio; Dr. Filippo Castoldi, Assessorato Alla Sanita, Regione Lombardia; Dr. Guglielmo D' Aurizio, Assessorato Alla Sanita, Regione Marche; Dr. Baronti Omelio, Assessorato Alla Sanita, Regione Toscana; Dr. Riccardo Galesso, Assessorato Alla Sanita, Regione Veneto; Dr. Migrelli Arrigo, Istituto Zooprofilattico Della Lombardia E Dell' Emilia; Dr. Silvamo Moca, Istituto Zooprofilattico Dell' Umbria E Delle Marche; Dr. Decastelli Lucia, Istituto Zooprofilattico Del Piemonte Della Liguria E Della Valle D' Aosta and Ms. Marina Paluzzi, Interpreter.

The United States government participants were Dr. Faizur R. Choudry, International Audit Staff Officer, TSC, FSIS; Dr. Oto Urban, International Audit Staff Officer, TSC, FSIS;

Dr. Ghias Mughal, Branch Chief, International Review Staff, FSIS; Ms. Ann Murphy, Agricultural Attaché, United States Embassy, Rome, and Mr. Franco Regini, Agricultural Specialist, Foreign Agricultural Service, United States Embassy, Rome.

The auditor explained to the GOI inspection officials that their inspection system was audited in accordance with the European Union/United States Veterinary Equivalence Agreement (Agreement). The auditors audited the meat inspection system against European Commission Directives, specifically (1) Council Directive 64/433/EEC of June 1964, (2) Council Directive 96/23/EC of April 29, 1996, and (3) Council Directive 96/22/EC of April 29, 1996. These three directives have been declared equivalent under the Agreement. In areas not covered by these directives, such as the requirement for daily inspection in processing establishments, the requirement for humane handling and slaughter of animals, the handling and disposal of inedible and condemned materials, and the requirement for species verification testing, the auditors audited against FSIS requirements and equivalence determinations, including the Pathogen Reduction/HACCP requirements. These requirements include regulations on HACCP, SSOP, and *E. coli* and *Salmonella* testing.

The following topics were discussed:

1. The lack of daily inspection coverage in establishments producing products for export to the U.S.
2. Inadequate inspection system controls, including the denaturing of condemned or inedible products, enforcement of humane slaughter laws, use of inspection procedures to check for disease, and carcass and offal inspection requirements.
3. Instances of actual product contamination and instances of the potential for direct product contamination.
4. The lack of monthly supervisory reviews of most certified establishments.
5. The continuing problems with the implementation and maintenance of SSOP in certified establishments.
6. The continuing problems with implementation and maintenance of HACCP systems in certified establishments.
7. Deficiencies in the *Salmonella* sampling and testing program.
8. Deficiencies in Italy's microbiological laboratory testing programs.
9. The lack of testing for species verification.
10. Deficiencies in the Instituti Zooproficlattici Sperimentali residue laboratories in Torino and Brescia concerning the laboratories' quality assurance programs.
11. The supervisory structure above the level of official veterinarian in the establishment is weak at best.

Ministry of Health officials stated that they would take the necessary steps to ensure that corrective actions and preventive measures are taken to address the noted deficiencies.

CONCLUSION

The Italian meat inspection system has major deficiencies, which demonstrate a lack of government oversight as evidenced by the findings presented in the report. However, a few improvements were observed in individual establishments' HACCP and SSOP programs.

The auditors found sanitation and other conditions to be so serious in four establishments that the establishments were delisted by the GOI. The auditors found significant problems in five establishments, which were then designated as marginal/re-review.

The GOI meat inspection officials stated that they would ensure prompt compliance. However, these assurances have been given previously at the conclusion of the May 2001 and September 2000 audits yet few, if any, corrective actions have been taken to date.

Dr. Faizur R. Choudry
International Audit Staff Officer

(signed)Dr. Faizur R. Choudry

ATTACHMENTS

A. Data Collection Instrument for SSOP
B. Data Collection Instrument for HACCP Programs
C. Data Collection Instrument for Generic *E. coli* testing.
D. Data Collection Instrument for *Salmonella* Testing
E. Laboratory Audit Forms
F. Individual Foreign Establishment Audit Forms
G. Written Foreign Country's Response to the Draft Final Audit Report *(no comments received)*

Attachment A

Data Collection Instrument for SSOP

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for SSOP were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written SSOP program.
2. The procedure addresses pre-operational sanitation.
3. The procedure addresses operational sanitation.
4. The pre-operational procedures address (at a minimum) the cleaning of food-contact surfaces of facilities, equipment, and utensils.
5. The procedure indicates the frequency of the tasks.
6. The procedure identifies the individuals responsible for implementing and maintaining the activities.
7. The records of these procedures and any corrective action taken are being maintained on a daily basis.
8. The procedure is dated and signed by the person with overall on-site authority.

The results of these evaluations were as follows: (see next page)

Est. #	1.Written program addressed	2. Pre-op sanitation addressed	3. Oper. sanitation addressed	4. Contact surfaces addressed	5. Fre-quency addressed	6. Respons-ible indiv. Identified	7. Docu-mentation done daily	8. Dated and signed
5-L	√	√	√	√	√	√	√	√
23-L	√	√	√	√	√	√	√	√
25-L	√	√	√	√	√	√	√	√
41-L	√	√	√	√	√	√	no	√
90-L	√	√	√	√	√	√	no	√
92 M/S	√	√	√	√	√	√	√	√
151-L	√	√	√	√	√	√	√	√
160-L	√	√	√	√	√	√	√	√
172-L	√	no	√	√	√	√	no	√
205-L	√	√	√	√	√	√	√	√
272 M/S	√	√	√	√	√	√	√	√
304 M/S	√	√	√	√	√	√	√	√
312 M/S	√	√	√	√	√	√	√	√
316-L	√	√	√	√	√	√	√	√
335-L	√	√	√	√	√	√	√	√
363-L	√	no	no	√	√	√	√	√
368-L	√	√	no	√	√	√	√	√
442-L	√	√	√	√	√	√	√	√
476-L	√	√	√	no	√	√	no	√
480-L	√	√	√	√	√	√	no	√
492-L	√	√	√	√	√	√	no	√
500-L	√	√	√	√	√	√	no	√
513-L	√	√	√	√	√	√	√	√
514-L	√	√	√	√	√	√	√	√
550-L	√	√	√	√	√	√	√	√
586-L	√	√	√	√	√	√	√	√
632-L	√	√	√	√	√	√	√	√
643 M/S	√	√	√	√	√	√	√	√
649-L	√	√	√	√	√	√	no	√
683-L	√	√	√	√	√	√	no	√
688-L	√	√	√	√	√	√	√	√
714-L	√	√	√	√	√	√	√	√
720-L	√	√	√	√	√	no	√	√
744-L	√	√	√	√	√	√	no	√
758-L	√	√	√	√	√	√	√	√
791 M/S	√	√	√	√	√	√	√	√
989-L	√	√	no	√	√	no	no	√
1170-L	√	√	√	√	√	√	no	√
1217-L	√	√	√	√	√	√	√	√
1223-L	√	√	√	√	√	√	√	√

Attachment B

Data Collection Instrument for HACCP Programs

Each of the establishments approved to export meat products to the U.S. was required to have developed and implemented a Hazard Analysis and Critical Control Point (HACCP) system. Each of these systems was evaluated according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. The establishment has a flow chart that describes the process steps and product flow.
2. The establishment has conducted a hazard analysis that includes food safety hazards likely to occur.
3. The analysis includes the intended use of or the consumers of the finished product(s).
4. There is a written HACCP plan for each product where the hazard analysis revealed one or more food safety hazard(s) reasonably likely to occur.
5. All hazards identified in the analysis are included in the HACCP plan; the plan lists a CCP for each food safety hazard identified.
6. The HACCP plan specifies critical limits, monitoring procedures, and the monitoring frequency performed for each CCP.
7. The plan describes corrective actions taken when a critical limit is exceeded.
8. The HACCP plan was validated using multiple monitoring results.
9. The HACCP plan lists the establishment's procedures to verify that the plan is being effectively implemented and functioning and the frequency for these procedures.
10. The HACCP plan's record-keeping system documents the monitoring of CCPs and/or includes records with actual values and observations.
11. The HACCP plan is dated and signed by a responsible establishment official.
12. The establishment is performing routine pre-shipment document reviews.

The results of these evaluations were as follows: (see next page)

Est. #	1. Flow diagram	2. Hazard analysis conducted	3. Use & users included	4. Plan for each hazard	5. CCPs for all hazards	6. Monitoring is specified	7. Corr. Actions are described	8. Plan validated	9. Adequate verific. procedures	10.Adequate documentation	11. Dated and signed	12.Pre-shipmt. doc. review
5-l	no	√	√	√	√	no	√	√	√	no	√	√
23-l	√	√	√	√	√	√	no	√	√	√	√	√
25-l	√	√	√	√	√	√	√	√	√	√	√	√
41-l	√	no	√	√	√	no	√	√	no	√	√	√
90-l	√	√	no	√	√	√	√	√	√	√	√	√
92ms	√	√	√	√	√	√	√	no	no	√	√	√
151-l	√	√	√	√	√	√	√	√	√	√	√	√
160-l	√	√	√	√	√	no	no	no	no	no	√	no
172-l	no	no	√	√	√	no	no	no	no	no	√	√
205-l	√	√	√	√	√	√	√	no	no	√	√	√
272ms	√	√	√	√	√	√	√	√	no	√	√	√
304ms	√	√	√	√	√	√	no	no	no	√	√	√
312ms	no	no	√	√	√	no	no	√	no	√	√	√
316-l	√	√	√	√	√	√	√	√	√	√	√	√
335-l	no	√	√	√	√	no	√	no	no	√	√	√
363-l	√	no	√	no	√	no	√	no	no	√	√	no
368-l	√	√	√	√	√	no	no	√	no	√	√	√
442-l	√	no	√	√	√	√	no	no	no	no	√	√
476-l	√	no	√	√	√	√	√	√	√	√	√	√
480-l	√	no	√	√	√	√	no	√	no	√	√	√
492-l	√	√	√	√	√	√	√	√	√	√	√	√
500-l	no	no	no	√	√	no	no	no	no	no	√	√
513-l	√	√	√	√	√	√	√	√	√	√	√	√
514-l	√	√	√	√	√	√	√	√	√	√	√	√
550-l	√	no	√	no	√	√	√	no	√	√	√	√
586-l	no	no	√	√	√	√	√	√	no	√	√	√
632-l	√	√	√	√	√	√	√	√	√	√	√	√
643ms	√	√	√	√	√	no	no	no	no	√	√	√
649-l	√	√	√	√	√	no	no	√	√	√	√	√
683-l	√	√	√	√	√	√	√	√	√	√	√	√
688-l	√	√	√	√	√	√	√	√	√	√	√	√
714-l	√	√	√	√	√	√	√	√	√	√	√	√
720-l	√	no	√	√	√	√	√	no	no	√	√	√
744-l	√	√	no	√	√	√	no	√	√	√	√	√
758-l	√	√	√	√	√	√	√	√	√	√	√	√
791ms	√	√	√	√	√	√	√	no	no	√	√	√
989-l	√	no	no	no	no	no	no	no	no	no	√	no
1170-l	√	√	√	√	√	√	√	√	√	√	√	√
1217-l	√	√	√	√	√	√	√	√	no	√	√	√
1223-l	√	√	√	√	√	√	√	√	√	√	√	√

Attachment C

Data Collection Instrument for Generic *E. coli* Testing

Each establishment was evaluated to determine if the basic FSIS regulatory requirements for generic *E. coli* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument contained the following statements:

1. The establishment has a written procedure for testing for generic *E. coli.*
2. The procedure designates the employee(s) responsible to collect the samples.
3. The procedure designates the establishment location for sample collecting.
4. The sample collection is done on the predominant species being slaughtered.
5. The sampling is done at the frequency specified in the procedure.
6. The proper carcass site(s) and/or collection methodology (sponge or excision) is being used for sampling.
7. The carcass selection is following the random method specified in the procedure or is being taken randomly.
8. The laboratory is analyzing the sample using an AOAC Official Method or an equivalent method.
9. The results of the tests are being recorded on a process control chart showing the most recent test results.
10. The test results are being maintained for at least 12 months.

Est. #	1.Written procedure	2. Sampler designated	3.Sampling location given	4. Predomin. species sampled	5. Sampling at the req'd freq.	6. Proper site or method	7. Sampling is random	8. Using AOAC method	9. Chart or graph of results	10. Results are kept at least 1 yr
92 ms	√	√	√	√	√	√	√	√	√	√
272ms	√	√	√	√	√	no	no	√	√	√
304 ms	√	√	√	√	√	no	no	√	√	√
312 ms	√	√	√	√	√	√	√	√	√	√
643ms	√	no	√	√	√	√	no	√	√	√
791 ms	√	√	√	√	√	√	√	√	√	√

6. Sequence for hog carcass sample site was belly, ham, jowl instead of ham, belly, jowl.

Attachment D

Data Collection Instrument for *Salmonella* Testing

Each slaughter establishment was evaluated to determine if the basic FSIS regulatory requirements for *Salmonella* testing were met, according to the criteria employed in the U.S. domestic inspection program. The data collection instrument included the following statements:

1. *Salmonella* testing is being done in this establishment.

2. Carcasses are being sampled.

3. Ground product is being sampled.

4. The samples are being taken randomly.

5. The proper carcass site(s) and/or collection of proper product (carcass or ground) is being used for sampling.

6. Establishments in violation are not being allowed to continue operations.

The results of these evaluations were as follows:

Est. #	*1. Testing as required*	*2. Carcasses are sampled*	3. Ground product is sampled	4. Samples are taken randomly	5. Proper site and/or proper prod.	6. Violative est's stop operations
92 M/S	√	√	N/A	√	√	√
272 M/S	√	√	N/A	no	no	√
304 M/S	√	√	N/A	no	no	√
312 M/S	√	√	N/A	√	√	√
643 M/S	√	√	N/A	√	√	√
791 M/S	√	√	N/A	√	√	√

5. Sequence for hog carcass sample site was belly, ham, jowl instead of ham, belly, jowl.

NOTE: Establishment personnel were collecting the samples under the direct supervision of GOI inspection officials.